



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,146	07/21/2000	Chryslain Sumian	BJA 254A	3940

7590 01/28/2002

Bolesh J Skutnik PhD JD
515 Shaker Road
East Longmeadow, MA 01028

EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 01/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,146

Applicant(s)

SUMIAN, CHRYSLAIN

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-2, 4-20 are pending in the instant application. Acknowledgement is made of Applicant's response to Office Action mailed 6/5/01.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 10, 11, 12, 14, 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (U.S. Pat. No. 4,292,299).

Suzuki teaches slow-releasing medical preparations that can be administered to wet mucous surface of a mucous membrane and skin of men or animals. The preparation has an adhesive layer and a non-adhesive layer; the adhesive layer has the property of swelling upon moistening, and as it swells, slowly releasing the medicament contained in the preparation. List of suitable polymers are contained in Table 1, col. 6.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-2, 4-5, 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. further in view of Schaefer et al. (U.S. Pat. No. 5,292,512).

As stated, Suzuki teaches a medical preparation containing an adhesive layer

Art Unit: 1616

and a non-adhesive layer to be administered to wet mucous of mucous surfaces and skin.

Schaefer teaches the use of microspheres containing active products for topical application. The microspheres are designed such that when the spheres enter the follicles, they diffuse the active product into the follicular canal and surrounding tissues. The microspheres can be made using polymers that swell. The Schaefer teaches that the benefit of using such microspheres is the active product can be brought specifically to the target regions with no secondary effects on the skin regions surrounding the follicular channel, in comparison to topical applications which do not have desired effectiveness because the epidermis forms a barrier.

It would have been obvious to one having ordinary skill in the art to use microspheres in the medical preparation of Suzuki's because they would want to target specific regions for treatment, as opposed to simply applying the topical application and risking secondary effects on nearby follicular channels (where treatment is not desired).

Response to Arguments

3. Applicant's arguments filed 10/19/01 have been fully considered but they are not persuasive.

The examiner would like to highlight certain teachings from the instant specification: "swellable composition" relates to composition containing specific kinds of substance which swells (page 8, 5th paragraph); "volume swelling" relates action that

Art Unit: 1616

increase physical volume occupied by the composition, such action including chemical reactions with another compound like water (page 9, 3rd paragraph).

Regarding the rejection under 35 U.S.C. 102(b), Applicant asserts that the skin surfaces containing hair follicles cannot be considered the same as the wet mucous surfaces described by Suzuki. This assertion is incorrect because Suzuki clearly teaches application to the wet mucous surface of skin of men and animals. It is inherent in the skin of men and animals that hair follicles are present.

Applicant next argues that because swelling in the instant invention must exert pressure on the hair follicle to prevent follicle collapse, and Suzuki does not teach thus, the instant invention is not anticipated. Suzuki clearly teaches the use of a polymer that swells; as it is inherent that such swelling action is physical and would exert pressure on the follicle, it is inherent that such swelling would prevent follicle collapse.

Applicant next argues that the instant invention does not require the use of a second composition layer. It is believed that this is a negative limitation that is not contained within the claims.

Lastly, Applicant asserts that the use of adhesive polymers as taught by Suzuki would prevent the compound from penetrating into the hair follicles. This assertion is neither supported by the specification, nor the claims, nor has Applicant submitted any data showing evidence that the use of adhesive polymers would materially affect the instant invention.

The rejection is maintained for the above reasons.

Regarding the rejection under 35 U.S.C. 103(a), Applicant's asserts that claims 2-5 and 9 stand rejected. This is an incorrect assertion. Claims 1, 13, 16, 17, and 18 were originally rejected.

In response to applicant's arguments against Schaefer individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant asserts that in Schaefer no swelling activity is described which takes place after the microsphere compound is applied to the skin. However, Schaefer clearly teaches using a polymer capable of swelling. One with ordinary skill would be motivated to use a swelling polymer as taught by Suzuki in order to obtain a slow-release of the medication contained within the microsphere when it is applied to the skin.

Applicant next argues that Schaefer does not disclose microspheres capable of swelling to force the hair follicle open. Schaefer does teach the penetration of follicle by the microspheres. Suzuki also clearly teaches using polymers that are capable of swelling on wet mucous surfaces and skin of men and animals. By using polymers capable of swelling on wet skin in microspheres, such microspheres would penetrate the skin and swell. It is inherent then that such swelling would force the hair follicle open.

Lastly, Applicant asserts that active ingredients must be added to Schaefer prior to application, in comparison to the instant invention that allows topical application of

Art Unit: 1616

drug solutions. In response it is noted that the features upon which applicant relies (i.e., topical application of drug solution) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The rejection is maintained based on the above reasoning.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

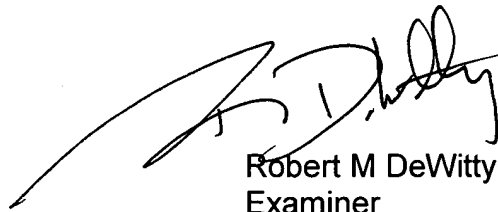
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

Art Unit: 1616

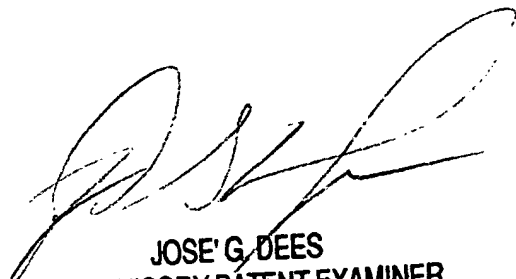
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Robert M DeWitty
Examiner
Art Unit 1616

January 17, 2002



JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616